IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC.,	)	
	)	
Plaintiff,	)	
	)	1:23-CV-629
v.	)	
	)	
NEOGENOMICS LABORATORIES, INC.,	)	
	)	
	)	
Defendant.	)	

ORDER

Natera, Inc. and NeoGenomics Laboratories, Inc. are research-focused healthcare companies that operate in the oncology testing industry. Both companies have products that can be used for earlier detection of cancer relapse. Natera seeks a preliminary injunction, contending that NeoGenomics' product, RaDaR, infringes two of Natera's patents. Because Natera has shown a likelihood of success on the merits that NeoGenomics is infringing the '035 patent and the other requirements for injunctive relief are met, the motion will be granted.

For purposes of this Order, the Court makes the following findings of fact and conclusions of law.

I. FACTS

As relevant here, Natera holds two method patents. Patent No. 11,519,035 issued on December 6, 2022, Doc. 1-2 at 2, and Patent No. 11,530,454 issued on December 20, 2022. Doc. 1-1 at 2. In simplified terms, the '035 patent provides methods and compositions for amplifying targeted genetic material while reducing amplification of

non-targeted genetic material. *See* Doc. 1-2 at 2, 89. The '454 patent provides methods, systems, and computer readable medium for detecting variations in genetic material indicative of disease or disease recurrence. *See* Doc. 1-1 at 2, 137.

Natera uses the methods described in these two patents in a product marketed under the brand name Signatera. *See* Doc. 9-18 at 2–3.[1] NeoGenomics offers a competing product under the brand name RaDaR. Doc. 94 at ¶ 10. RaDaR has been used in clinical cancer research since April 2020.[2] *Id.* at ¶ 11. It has been commercially available since March 2023. *Id.* at ¶ 15.

Signatera and RaDaR each work by identifying circulating DNA fragments from cancer cells within the bloodstream. *See* Doc. 13 at ¶ 125; Doc. 94 at ¶ 10. The presence of these tumor DNA fragments can indicate the efficacy of cancer treatment and the risk of cancer recurrence. Doc. 7 at ¶ 23; Doc. 13 at ¶ 34.

During a cell's life cycle, it naturally sheds short fragments of DNA into the bloodstream. Doc. 13 at ¶ 36. These DNA fragments are referred to as cell-free DNA (cfDNA). *Id.*; Doc. 97 at ¶ 43. Both healthy cells and cancerous cells create cfDNA. Doc. 13 at ¶ 36. The subset of cfDNA that comes from cancer cells is referred to as circulating tumor DNA (ctDNA). *Id.*; Doc. 97 at ¶ 247.

[1] Throughout this Order, the Court has cited some of the evidence in the record that supports its factual findings but has made no attempt to cite all the evidence supporting its findings.

[2] RaDaR was initially offered by a company known as Inivata. Doc. 94 at ¶ 11. NeoGenomics acquired Inivata in 2021. *Id.* at ¶ 12.

If a patient has a positive response to cancer treatment, the patient's tumor typically decreases in size, eventually becoming undetectable in radiographic imaging or clinical examination. Doc 13 at ¶ 34. If tumor cells remain in a patient's body after treatment, there is the potential for cancer relapse, either locally or through metastases. *Id.* Molecular residual disease (MRD) refers to the presence of small amounts of tumor DNA molecules in the body after treatment. *Id.*; Doc. 7-38 at 2. Early detection of MRD supports better patient outcomes. Doc. 13 at ¶ 34.

MRD tests are either tumor informed or tumor naïve. Doc. 7 at ¶ 24. Tumor informed tests are designed from a patient's genetic information obtained from a tissue biopsy of the patient's tumor. *Id.* These bespoke tests are often preferred by doctors and are seen as highly sensitive because they are personalized to the patient. *Id.* at ¶¶ 34–35; Doc. 92-1 at 4, 17. Tumor naïve tests can provide faster results but are less favored by doctors because they are perceived to be less accurate. Doc. 7 at ¶¶ 34–35.

Signatera, Natera's product, and RaDaR, NeoGenomics' product, are tumor informed MRD tests that work by detecting trace amounts of ctDNA in a patient's bloodstream. *See* Doc. 13 at ¶¶ 115, 125; Doc. 94 at ¶ 10. Patients known to have cancer first provide tumor tissue samples. Doc. 13 at ¶ 118; Doc. 94 at ¶ 10. Next, the DNA from those tissue samples is sequenced, and the DNA information is used to design liquid biopsy MRD assays. Doc. 13 at ¶¶ 118–19; Doc. 94 at ¶¶ 9–10. After cancer treatment ends, patients regularly provide blood samples for testing. Doc. 13 at ¶ 120; Doc. 94 at ¶ 10. Using tumor informed MRD assays, doctors and scientists can detect DNA from cancer cells in the blood in the form of ctDNA. Doc. 13 at ¶¶ 120–22; Doc. 94 at ¶ 10.

Natera is the leader in the MRD assay market. *See* Doc. 7 at ¶¶ 45, 73; Doc. 92-1 at 2; Doc. 11-9 at 42. According to one report, Natera has 74% of the total market share for both tumor informed and tumor naïve tests. Doc. 92-1 at 12, 17. RaDaR is the only other tumor informed MRD test available for clinical use and covered by private insurance.[3] *See* Doc. 7 at ¶ 48. Other companies, such as Guardant Health, compete in the MRD space, but they offer tumor naïve products, not tumor informed products. *See id.* at ¶ 53; Doc. 92-1 at 17. The MRD testing market is expected to grow substantially over the next few years. Doc. 92-1 at 3–4.

Additional findings of fact will be stated as they become relevant.

II. PRELIMINARY INJUNCTION STANDARD

Courts have the power to grant preliminary injunctions in patent infringement lawsuits. *See High Tech Med. Instrumentation, Inc. v. New Image Indus. Inc.*, 49 F.3d 1551, 1554 (Fed. Cir. 1995); 35 U.S.C. § 283. To establish a preliminary injunction is warranted, the patentee seeking an injunction must show: "(1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest." *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022) (quoting *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008)) (cleaned up).

[3] Until recently, Invitae offered another tumor informed MRD test under the brand name PCM. After a jury in the District of Delaware found that product infringed other patents held by Natera, the court permanently enjoined Invitae from offering PCM for clinical use. *See* Doc. 164-1 (redacted permanent injunction entered in *Natera, Inc. v. ArcherDX, Inc.*, No. 20-CV-125 (D. Del. Nov. 21, 2023)).

III. SUCCESS ON THE MERITS

To show a likelihood of success on the merits, the moving party must demonstrate "(1) it will likely prove infringement and (2) its infringement claim will likely withstand challenges to the validity and enforceability of the patents." *See Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001) (cleaned up). In patent cases, the likelihood of success factor is governed by Federal Circuit law. *See ABC Corp. I v. P'ship and Unincorporated Ass'ns Identified on Schedule "A"*, 52 F.4th 934, 941 (Fed. Cir. 2022). When evaluating the likelihood of success, courts consider all the burdens and presumptions that would apply at trial. *See Purdue*, 237 F.3d at 1363.

To assess the likelihood of infringement, courts first "determine the scope and meaning of the patent claims asserted." *Oakley, Inc. v. Sunglass Hut. Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (cleaned up); *see also CommScope Techs. LLC v. Dali Wireless Inc.*, 10 F.4th 1289, 1295 (Fed. Cir. 2021). Then "the properly construed claims are compared to the allegedly infringing device." *Oakley*, 316 F.3d at 1339 (cleaned up). Infringement claims must also withstand any challenges to a patent's validity and enforceability. *See Purdue*, 237 F.3d at 1363.

IV. '035 PATENT – LIKELIHOOD OF SUCCESS ON THE MERITS

A. Infringement

For purposes of the preliminary injunction motion, Natera asserts that the RaDaR product offered by NeoGenomics infringes claims 1, 12, and 13 of the '035 patent. Doc. 71-4 at 2. Claim 1 states:

> A method for amplifying and sequencing DNA, comprising:
> tagging isolated cell free DNA with one or more universal tail adaptors to generate tagged products, wherein the isolated cell-free DNA is isolated from a blood sample collected from a subject who is not a pregnant woman;
> amplifying the tagged products one or more times to generate final amplification products, wherein one of the amplification steps comprises targeted amplification of a plurality of single nucleotide polymorphism (SNP) loci in a single reaction volume, wherein one of the amplifying steps introduces a barcode and one or more sequencing tags; and
> sequencing the plurality of SNP loci on the cell free DNA by conducting massively parallel sequencing on the final amplification products, wherein the plurality of SNP loci comprises 25–2,000 loci associated with cancer.

Doc. 1-2 at 213. Amplification refers to increasing "the number of copies of a molecule, such as a molecule of DNA." *Id.* at 109.

Natera has made a strong showing that the RaDaR test made and sold by NeoGenomics uses the method claimed in the '035 patent and infringes the '035 patent. It is likely to succeed on the merits of its infringement claim.

NeoGenomics contends that the claims at issue require targeted amplification of already tagged DNA and that RaDaR does not use targeted amplification on tagged products. *See* Doc. 89 at 11–12; Doc. 97 at ¶¶ 89–93. But this ignores the fact that RaDaR first tags the products with the CS1 adaptor sequence, then performs targeted amplification to tag the products a second time with the CS2 sequence. *See* Doc. 13 at ¶¶ 44, 88 (explaining RaDaR uses teachings of Forshew); Doc. 145-1 at 57, 60 (discussing PCR amplification and CS1 and CS2 tagging in Forshew). Thus, RaDaR amplifies "the tagged products one or more times to generate final amplification products, wherein one of the amplification steps comprises targeted amplification." Doc.

1-2 at 213. Natera has shown a likelihood of success on the merits on its claim that NeoGenomics infringes Claim 1 of the '035 patent.

NeoGenomics also contends that the dependent Claims 12 and 13 require that the tagging referenced in Claim 1 occur over two rounds of polymerase chain reaction (PCR)[4] because Claims 12 and 13 refer to a first primer comprising a first universal tail adaptor and a second primer comprising a second universal tail adaptor. *See* Doc. 89 at 12; Doc. 1-2 at 213. But an independent claim like Claim 1 is "broader than the claims that depend from it," *Littlefuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022), and "each claim in a patent is presumptively different in scope." *Trs. of Columbia Univ. in N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016).

When a limitation found in a dependent claim is the only meaningful difference between the dependent and independent claim, "the independent claim is not restricted by the added limitation in the dependent claim." *Id.*; *see also Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007) (holding that proposed claim readings should not make the independent and dependent claims identical in scope). This argument does not weaken Natera's likelihood of success on the merits as to infringement of Claim 1.

B. Validity

To show a likelihood of success, the patent holder must demonstrate a patent is likely to withstand any challenges to validity. *See Purdue*, 237 F.3d at 1363. A patent is presumed valid. *Id.* at 1365; *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 412 (2007).

[4] PCR is a common method of amplification. *See* Doc. 141-6 at 7.

The party challenging the validity of a patent must come forward with evidence that raises a substantial question of validity. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). The patentee then has the "burden of responding with contrary evidence." *Id.* at 1377. If the patentee does not prove the validity question "lacks substantial merit," courts will deny the motion for a preliminary injunction. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001).

NeoGenomics challenges the validity of the '035 patent on several grounds, primarily contending that it is obvious. *See* Doc. 89 at 15–16. NeoGenomics also makes shorthand or conclusory arguments that there are issues with the patent's written description, that Natera did not properly explain changes made to the named inventors, and that the '035 patent covers patent-ineligible subject matter. *See id.* at 16–17, 19.

1. Obviousness

A patent cannot issue when "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art." 35 U.S.C. § 103; *see also Teleflex*, 550 U.S. at 406–07. A party seeking to show a patent is invalid on obviousness grounds must show that "a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so." *Regents of Univ. of Cal. v. Broad. Inst.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018).

An invention is not automatically obvious just because a motivation to combine may exist, *see Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.,* 876 F.3d 1350,

1359–60 (Fed. Cir. 2017), or "because all of the claimed limitations were known in the prior art at the time of the invention." *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, 918 F.3d 928, 934 (Fed. Cir. 2019). A challenger asserting obviousness must give "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Mere conclusory statements tend to show hindsight bias, not that the invention is obvious. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012).

The priority date for the claims of the '035 patent is May 18, 2011, *see* Doc. 1-2 at 2; Doc. 138-2 at 7–8, so the prior art must be from before this date. NeoGenomics first asserts that the Fluidigm Access Array System, discussed in the 2010 Kaper publication renders the '035 patent obvious. *See* Doc. 89 at 15–16; Doc. 97-14 (abstract); Doc. 97-15 (poster). But Dr. Kaper used DNA samples from tumor tissue, not cfDNA, in discussing Access Array. *See* Doc. 141 at ¶ 156.

NeoGenomics contends that it would have been obvious to modify Access Array for cfDNA because cfDNA was known at this time to be useful for cancer detection. *See* Doc. 89 at 15; Doc. 97 at ¶¶ 240–41. But there were many well-known barriers to using cfDNA. *See* Doc. 141 at ¶ 157 (Tumor tissue samples provide tumor-associated DNA in greater quantity than the ctDNA found in cfDNA.); Doc. 141-2 at 2 (Cell-free DNA is fragmented and exists in low yield within the body.); Doc. 13-7 at 2 (Circulating tumor DNA is just a subset of cfDNA and exists in even lower yields.); Doc 141 at ¶ 16 (Even if a cfDNA molecule has a SNP of interest, the cfDNA may be fragmented such that it "does not contain sites for both primers of a primer pair to bind" and the SNP will not

amplify "successfully when PCR is performed."). These challenges associated with cfDNA, and others, presented obstacles to successfully amplifying and sequencing ctDNA with precision during the relevant time period, *see* Doc. 141-2 (published October 2016); Doc. 141 at ¶¶ 19–21, making it unlikely a person skilled in the art would have been motivated to use cfDNA with Access Array and would have anticipated success in doing so. *See Forest Lab'ys*, 918 F.3d at 934; *Arctic Cat*, 876 F.3d at 1359–60.[5] NeoGenomics' assertions about Access Array appear to show hindsight bias more than they support a substantial question of obviousness. *ActiveVideo*, 694 F.3d at 1327.

In passing, NeoGenomics also contends that something called "ARM-PCR" renders the '035 patent obvious for "similar reasons." Doc. 89 at 15. This conclusory assertion does not raise a substantial question of validity.[6]

2. Written Description

Title 35 U.S.C. § 112 requires a patent specification to contain a written description of the invention that "discloses and teaches" what is claimed. *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010); 35 U.S.C. § 112(a). There is no required "particular form of disclosure," and the written description need not use the

[5] At oral argument, Natera's counsel said that Natera had also invented ways to overcome these barriers.

[6] In support of this half-a-sentence argument, NeoGenomics provides a bulk citation to some 68 paragraphs covering well over 10 pages in a declaration from one of its experts, *see* Doc. 89 at 15, citing Doc. 97 at ¶¶ 235–303. Expert declarations are not substitutes for briefs and implicit attempts to incorporate them by reference cannot be used to avoid the word limits for briefing. *See* discussion *infra* at 13.

exact words of the claims. *See Ariad*, 598 F.3d at 1352; *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922–23 (Fed. Cir. 2004).

NeoGenomics contends that the specification for the '035 patent "lack[s] examples of the claimed processes" and "[t]he claims are disassociated from the described invention." *See* Doc. 89 at 17. This argument, made in one paragraph, does not raise a substantial question of validity.[7]

3. Inventorship

The named inventors in an issued patent are presumed correct. *Eli Lilly and Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004). A "party seeking correction of inventorship must show by clear and convincing evidence that a joint inventor should have been listed." *Blue Gentian, LLC v. Tristar Prods., Inc.*, 70 F.4th 1351, 1357 (Fed. Cir. 2023) (citing *Aradigm*, 376 F.3d at 1358). While a patent must reflect true inventorship, "a patent cannot be invalidated if inventorship can be corrected instead." *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020).

Correcting inventorship for an issued patent can be done either by petition to the Director of the U.S. Patent and Trademark Office or by court order. *See* 35 U.S.C.

[7] In support of its perfunctory "disassociation" argument, Natera again provides a bulk citation to over 20 paragraphs of an expert's declaration. *See* Doc. 89 at 17, citing Doc. 97 at ¶¶ 404–26. But most of those paragraphs are addressed to the '454 patent, and such bulk citations do not direct the Court's attention with any specificity to facts relevant to the '035 patent. *See* Doc. 27 at ¶ 1 (Order requiring that citations to a multi-page exhibit "must contain a pin cite to the specific page" or "paragraph number"). The Court is not required to sift through blocks of evidence itself to locate the truffles. *See Hughes v. B/E Aerospace, Inc.*, No. 12-CV-717, 2014 WL 906220, at *1 n.1 (M.D.N.C. Mar. 7, 2014) ("A party should not expect a court to do the work that it elected not to do."). As the Court has stated, *see supra* note 6, at 10 and discussion *infra* at 13, expert declarations are not mechanisms to avoid word limits.

§§ 256(a), (b). Inventorship in a patent application can also be corrected, 35 U.S.C. § 116(c), and the patent office does not require an explanation for the correction. *See* 37 C.F.R. § 1.48 (setting out requirements for correction of inventorship in provisional and nonprovisional patent applications).

NeoGenomics does not show by clear and convincing evidence that an inventor is missing from the '035 patent. *See Blue Gentian*, 70 F.4th at 1357. In fact, NeoGenomics does not raise any issues with any specific inventor of the '035 patent, saying only that the changes Natera made during the patent application process "appear dubious." *See* Doc. 89 at 19. This perfunctory assertion does not raise a substantial question of invalidity for the '035 patent based on inventorship.

4. Patent Ineligible Subject Matter

In arguing that the '035 patent is not valid because of ineligible subject matter, NeoGenomics purports to incorporate by reference an argument made in another brief. Doc. 89 at 19 (referencing NeoGenomics' motion to dismiss brief, Doc. 52). The Court will disregard this argument for purposes of this motion.

The Local Rules limit briefs in support of motions and responsive briefs to no more than 6,250 words. *See* LR 7.3(d). Per this Court's standard order, when a party incorporates arguments made in other briefs, the incorporating brief's word count is "correspondingly decreased." Doc. 27 at ¶ 1. The word count in the incorporated brief, Doc. 52, is some 6,233 words. The word count in the incorporating brief, Doc. 89, excluding the incorporated argument, is some 6,218 words. NeoGenomics has thus attempted to surpass the word limit by thousands of words.

Word or page limits are common across courts of all stripes for obvious reasons; among other things, such limits require parties to avoid rhetoric and to present their best arguments, and they facilitate prompt, efficient resolution of cases. Efforts to circumvent word limits by incorporating briefs by reference or dividing one motion into several motions are improper. *See, e.g.*, *Basulto v. Netflix, Inc*., No. 22-CV-21796, 2022 WL 17532279, at *2 (S.D. Fla. Dec. 8, 2022) (collecting cases); *Monec Holding AG v. Motorola Mobility, Inc.*, No. 11-CV-798, 2014 WL 4402825, at *2 (D. Del. Sept. 5, 2014) (finding opposing party prejudiced if forced to respond to legal arguments in incorporated exhibit); *Aircraft Tech. Publishers v. Avantext, Inc.*, No. 7-CV-4154, 2009 WL 3833573, *1 (N.D. Cal. Nov. 16, 2009) (striking summary judgment motions that were improperly filed separately to avoid page limits).

At the preliminary injunction hearing,[8] NeoGenomics focused on the arguments it made in its preliminary injunction opposition brief, not the incorporated brief about patent ineligible subject matter. The Court declines to consider the subject matter arguments in connection with the preliminary injunction motion.

C. Conclusion

Natera has demonstrated a likelihood of success on the merits for its '035 patent infringement claim. RaDaR likely infringes Claim 1 of the '035 patent, and NeoGenomics has not raised a substantial question of validity.

[8] At the Court's request, the deputy clerk had advised the parties several days before the hearing of a number of matters the Court wanted addressed, one of which was the effort to avoid the word limits by incorporating another brief.

V. '454 PATENT – LIKELIHOOD OF SUCCESS ON THE MERITS

In view of its findings and conclusions on the '035 patent, the Court need not address whether Natera has shown a likelihood of success on its claim that the '454 patent is valid and infringed.

VI. IRREPARABLE HARM

A. Likelihood of Irreparable Harm

The plaintiff seeking preliminary injunctive relief must show a likelihood of irreparable harm. *BlephEx*, 24 F.4th at 1398. A patentee suffers irreparable harm when "forced to compete against products that incorporate and infringe its own patented inventions." *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013). Natera will likely suffer irreparable harm if NeoGenomics continues to offer RaDaR in the marketplace.

Evidence of head-to-head competition, lost market share, lost sales, and a decline in reputation and brand distinction can support a showing of irreparable harm. *See TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 793 (Fed. Cir. 2019); *Douglas Dynamics*, 717 F.3d at 1344. When two competitors directly compete "for the same customers in the same markets," irreparable harm is evident. *See Presidio Components Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012).

Natera and NeoGenomics are direct competitors in the tumor informed MRD marketplace. *See* Doc. 7 at ¶ 131; Doc. 92-1 at 26. Indeed, NeoGenomics is Natera's only competitor in this market. *See supra* note 3, at 4. Analysts believe NeoGenomics' RaDaR will see significant growth in the industry. Doc. 92-1 at 5, 20. For many of

NeoGenomics' sales, Natera will lose out on potential customers, profits, business relationships, and clinical opportunities. *See Douglas Dynamics*, 717 F.3d at 1345 (holding infringer's increase in market share more relevant than patentee's ability to maintain market share).

In this industry, biopharmaceutical partnerships are important. Doc. 7 at ¶¶ 103–04. By participating in clinical trials, companies can generate product data, gain credibility in the marketplace, and contribute to published research. *Id.* at ¶¶ 79, 103. Data from clinical trials also creates the support needed for insurance coverage determinations and entry into the larger clinical marketplace. *Id.* at ¶¶ 77, 103. If forced to compete against RaDaR for participation in future clinical studies, Natera could lose out on partnerships that substantially impact Signatera's future success, a loss that is challenging to quantify. *Id.* at ¶ 105; *see also Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017) (holding that "[w]here the injury cannot be quantified" and "no amount of money damages is calculable," the harm is irreparable).

Natera has a first mover advantage as a pioneer in the tumor informed MRD market. Doc. 7 at ¶ 134. This advantage includes a period of exclusivity, in which Natera can establish brand recognition, customer loyalty, and business foundations. *Id.* at ¶ 136. Natera has never licensed the '035 patent, Doc. 14 at ¶ 16, and it has a right to exclusivity as the patent holder. *See Douglas Dynamics*, 717 F.3d at 1345; *Presidio*, 702 F.3d at 1363 (finding unwillingness to license supported irreparable injury). Natera's position as first mover will be unfairly cut short if RaDaR remains on the market.

NeoGenomics contends that the larger MRD market is the relevant market, and that Guardant Health is a bigger competitor for Natera than NeoGenomics. Doc. 89 at 23–24. While Guardant Health does operate in the MRD testing space, Doc. 92-1 at 26, it offers a tumor naïve product. *See* Doc. 7 at ¶ 53. Market analysts have confirmed that tumor informed tests are preferred by oncologists, Doc. 92-1 at 4, 17, making it highly likely that for many oncologists, the only two products are Natera's test and NeoGenomics' likely infringing test.

Even viewed as part of the larger MRD market, there is still irreparable harm. As the Federal Circuit has noted, "the existence of a two-player market" supports the granting of an injunction "because it creates an inference that an infringing sale amounts to a lost sale for the patentee," but "the converse is not automatically true." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011) (cleaned up).

NeoGenomics contends that Natera has not shown that it has lost any contracts to NeoGenomics. But Natera has shown Moderna used RaDaR in at least one clinical study, Doc. 14-7 at 2, 11, and that NeoGenomics' representatives are promoting RaDaR to Natera's customers. Doc. 18-6. There is not abundant evidence of lost sales, but RaDaR is relatively new to the market; it has only been commercially available since March, Doc. 14-4, and it only received approval for Medicare coverage for use with certain specified cancers in July. Doc. 1-30. Competition and potential lost sales from RaDaR are likely to occur and cause harm.

Finally, NeoGenomics contends that Natera unreasonably delayed in filing this action. *See* Doc. 89 at 20–22. Natera received this patent in December 2022, Doc. 1-2 at

2, NeoGenomics entered the clinical market in March 2023, Doc. 14-4, and this lawsuit was filed in July 2023. Doc. 1. In the interim, Natera was already involved in ongoing patent infringement litigation over related patents. *See ArcherDX, Inc.*, No. 20-CV-125.

This is not undue delay. A patentee is not required to "sue all infringers at once" and suing four months after an infringer enters the market is relatively quick. *Robert Bosch*, 659 F.3d at 1151. Moreover, "picking off one infringer at a time is not inconsistent with being irreparably harmed." *Id.* (citing *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005)).

Natera has shown a likelihood of irreparable harm.

B. Causal Nexus

In addition to likely irreparable harm, the patentee must also demonstrate "that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Bio-Rad Lab'ys, Inc. v. 10X Genomics, Inc.*, 967 F.3d 1353, 1377–78 (Fed. Cir. 2020) (cleaned up); *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 809 F.3d 633, 640 (Fed. Cir. 2015). While the infringing feature does not have to be the sole reason a product is bought, *Apple*, 809 F.3d at 641–42, a causal nexus exists if "the infringing feature drives consumer demand for the accused product." *TEK Glob.*, 920 F.3d at 792 (quoting *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375–76 (Fed. Cir. 2012)).

There is a causal nexus between the likely infringement and harm. It appears highly likely that NeoGenomics' predecessor built RaDaR using the methods of the '035 patent as a foundation. As previously discussed *supra*, the likely infringement allows NeoGenomics to offer RaDaR as a tumor informed MRD assay, doctors who order these

tests often prefer tumor informed tests, and RaDaR's ability to perform tumor informed testing is what drives consumer demand for it.

C. BALANCE OF EQUITIES

The third factor requires the patentee show that "the balance of equities tips in its favor." *BlephEx*, 24 F.4th at 1398. When balancing equities, the court "weigh[s] the harm to the moving party if the injunction is not granted against the harm to the non-moving party if the injunction is granted." *Metalcraft*, 848 F.3d at 1369 (citing *Hybritech Inc. v. Abbott Lab'ys*, 849 F.2d 1446, 1457 (Fed. Cir. 1988)). The court "may consider the parties' sizes, products, and revenue sources" in its analysis, but the "expenses incurred in creating the infringing products and the consequences of its infringement are irrelevant." *Bio-Rad Lab'ys*, 967 F.3d at 1378 (cleaned up).

The balance of equities weighs in favor of granting a preliminary injunction. A 2020 analyst report identified Signatera as Natera's "most valuable offering." Doc. 7 at ¶ 158. In 2023, that same firm predicted that advances related to Signatera were key to Natera's future success. *See* Doc. 7-18 at 4 (section titled "Key catalysts for Natera's stock from here").

A May 2023 report predicts revenue from Signatera will increase from $130.4 million in 2022 to $432.4 million in 2025 and make up 52.1% of Natera's total growth in revenue. Doc. 7 at ¶¶ 156–57; Doc. 7-18 at 6. In the first quarter of 2023, the "vast majority" of Natera's revenue attributable to oncology products came from "clinical Signatera volume growth." Doc. 7-18 at 4 (section titled "More on Signatera in greater detail"). Signatera is important to Natera's economic success.

In contrast, NeoGenomics is not as dependent on RaDaR's success. It has "the broadest cancer diagnostic testing menu in the U.S.," with over 600 tests related to cancer diagnostics; NeoGenomics launches roughly 60 to 70 new test products each year. Doc. 7-19 at 3 (April 2023 report, section titled "Investment Thesis").

RaDaR also only recently became commercially available. *See* Doc. 14-4. Although NeoGenomics spent a significant amount of money acquiring Inivata and the RaDaR test, this expense does not tip the balance of equities in favor of NeoGenomics. *See Bio-Rad Lab'ys*, 967 F.3d at 1378.

The harm to Natera if a preliminary injunction is not granted outweighs the harm to NeoGenomics in granting the injunction. *See Metalcraft*, 848 F.3d at 1369. Signatera has been on the market longer and is predicted to be a major contributor to Natera's future success. In comparison, RaDaR is relatively new to the market and is not a major product in NeoGenomics' portfolio. Natera's projected revenue streams and dependence on Signatera tips the balance of equities in favor of granting the preliminary injunction. *See Bio-Rad Lab'ys*, 967 F.3d at 1378.

D. PUBLIC INTEREST

It is in the public's interest to uphold patent rights. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 863 (Fed. Cir. 2010); *Douglas Dynamics*, 717 F.3d at 1346 (stating the public has a "general interest in the judicial protection of property rights in inventive technology"). Before granting an injunction, courts must balance "protecting the patentee's rights" with any adverse effects on the public. *i4i*, 598 F.3d at 863; *see also Metalcraft*, 848 F.3d at 1369 ("[T]he district court should focus on whether a critical

public interest would be injured by the grant of injunctive relief."). To reduce any adverse effects on the public interest, an injunction can be crafted to exclude current users of the enjoined product. *See i4i*, 598 F.3d at 863.

The public interest in enforcing patent rights tips in favor of granting a preliminary injunction. Anyone in need of a tumor informed MRD test will be able to get one from Natera; Signatera is clinically validated for use with the same cancers as RaDaR. *See* Doc. 10-39 at 2–3 (RaDaR cancer coverage); Doc. 10-5 at 2 (Signatera's Medicare coverage); Doc. 10-15 at 13 (listing Signatera's published indications as of 2022). Natera has the capacity to take on more customers. *See, e.g.*, Doc. 10-13 at 7 (Form 10-K for 2021 discussing Natera's "global network of over 100 laboratory and distribution partners"); Doc. 10-17 at 17 (2022 presentation discussing Natera's ability to scale up); Doc. 14 at ¶ 14; *see also* Doc. 7 at ¶¶ 89–92. The injunction can be crafted in a way that does not disrupt clinical trials and ongoing research and so that current patients can continue to use RaDaR. *See* discussion *infra.*

Consumer choice is important, as NeoGenomics points out. Doc. 89 at 30–31. But competition from an infringing product does not benefit the public, and it impedes innovation. *See Douglas Dynamics*, 717 F.3d at 1346 (so holding after verdict in favor of patent holder). While this is not a final decision on the merits, Natera has made a strong case for infringement and validity of the '035 patent. The need to protect consumer choice does not weigh heavily in favor of denying an injunction, in light of other evidence. *See Shure, Inc. v. ClearOne, Inc.*, No. 17-CV-3078, 2019 WL 3555098, at *25 (N.D. Ill. Aug. 5, 2019).

As NeoGenomics points out, there are patients currently using RaDaR who would be harmed if it were withdrawn from the market, and there are clinical trials and research projects, which depend on the use of RaDaR, in process or approved to begin. *See* Doc. 89 at 31. The public interest does not support enjoining these uses, despite the potential for infringement.

The public generally benefits from clinical trials, which should be carried out if they have been approved and completed if they are in process. The same is true for research projects already in process. And, as Natera recognizes, current patients using RaDaR, whether in clinical trials or otherwise, cannot at this point in their medical care use Signatera as a substitute. *See* Doc. 5 at 31 (asking for an injunction that allows patients currently using RaDaR to continue use); Doc. 139 at 19. The Court agrees that avoiding disruption to ongoing treatment, research, and clinical studies is proper, and the preliminary injunction will be crafted to protect those interests.

E. CONCLUSION

Natera has shown that it is likely to succeed on the merits, it is likely to suffer irreparable harm in the absence of preliminary relief, the balance of equities tips in its favor, and an injunction is in the public interest. A preliminary injunction is appropriate.

It is **ORDERED** that Natera's preliminary injunction motion, Doc. 5, is **GRANTED.** The preliminary injunction will issue separately.

This the 27th day of December, 2023.

UNITED STATES DISTRICT JUDGE